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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.**	**Applicant(s)**	
	10/682,584	TAS ET AL.	
	Examiner	**Art Unit**	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 3/13/2006 has been entered.

Response to Arguments

Applicants' arguments, filed 3/13/2006, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-12 are currently pending and are the subject of this Office Action. Claims 13-28 have been cancelled. This is the first Office Action on the merits of the application after the filing of a Request for Continued Examination.

Information Disclosure Statement

The information disclosure statements filed 3/13/2006 and 5/03/2006 fail to comply with the provisions of 37 CFR § 1.97, 1.98 and MPEP § 609 because: References CAF, CAG and

CAH of the 5/03/2006 IDS are not full citations and were therefore not considered. They have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in these information disclosure statements or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR § 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-12 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of inducing cellular differentiation and/or apoptosis in basal cell carcinoma tumors by administering cyclopamine, does not reasonably provide enablement for inducing cellular differentiation and/or apoptosis in all tumors by administering cyclopamine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

In re Wright, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and

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[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to methods of inducing differentiation and/or apoptosis in tumor cells that use the Hedgehog/Smoothened (*Hh/Smo*) signaling for inhibition of differentiation and/or apoptosis. The claimed methods induce said differentiation and/or apoptosis through the administration of cyclopamine. The relative skill of those in the art is high, generally that of an M.D. or Ph.D. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites Sanchez *et al.* (Mechanisms of Development, 2005, vol. 122, pages 223-230). This article plainly demonstrates that the art of inducing differentiation and/or apoptosis by administering cyclopamine is very unpredictable. As discussed in Sanchez *et al.*, a dosing schedule of cyclopamine that inhibited tumor cell proliferation as well as tumor growth *in vivo* did not necessarily cause a significant induction of tumor cell apoptosis. Analysis showed that *Hh/Smo* signaling activity was inhibited in the cyclopamine-treated mice, however, despite marked inhibition of tumor cell proliferation, analyses of tumors for apoptosis revealed no significant differences between vehicle-treated and cyclopamine-treated mice (Fig. 3). Sanchez *et al.* also indicate that the induction of tumor cell apoptosis *in vitro* is dependent on the quantity and duration of application of cyclopamine.

Further, applicant's arguments filed on June 24, 2005 and March 13, 2006 provide additional evidence that the art of inducing differentiation and/or apoptosis in tumor cells is extremely unpredictable. For example, applicant's state:

> The fact that cyclopamine or a derivative thereof were actually applied in prior art on transformed cells and were found not to cause cell death at concentrations causing inhibition of the *Hh/Smo* signaling and of cellular proliferation is evidence that the inductions of the apoptosis and/or differentiation of tumor cells are not inherently present in the prior art uses of said compounds. Applicant's Arguments, May 3, 2006 (page 7).

Applicants further disclose in the same reply that studies have been published after the filing date of the present application that demonstrate the responses of cells to the inhibition or upregulation of *Hh/Smo* signaling in terms of differentiation or apoptosis or proliferation "depend on the cell types, their environment, as well as on the means, extent and duration of the inhibition or upregulation of *Hh/Smo* signaling."

Applicants also discuss patent application 60/240,564 in their reply filed on March 13, 2006. In this discussion, applicants state that the experimental findings in '564 teach to the skilled artisan that "uses of cyclopamine that cause inhibition of *Hh/Smo* signaling do not cause cell death in the cells exhibiting constitutive activation of *Hh/Smo* signaling." Further, "inhibition of *Hh/Smo* signaling by cyclopamine or a derivative thereof do not cause cell death in the cells lacking a functional Ptc". See page 10 of March 13, 2006 response.

According to applicants, numerous publications in the prior art and afterwards have demonstrated that, in terms of cellular proliferation, "upregulation of *Hh/Smo* signaling can be stimulatory and the inhibition of said signaling can be inhibitory for certain types of cell types but different cell types in the same organism can respond very differently, even in the opposite directions to the same modulation of *Hh/Smo* signaling" and " proliferation of certain primary tumor cells is stimulated by cyclopamine." See page 11 of March 13, 2006 response.

In the reply filed 6/24/2005, applicants state on page 36/40 that "studies published since the filing of this application have confirmed that responses of cells to cyclopamine in terms of both cellular differentiation and apoptosis depend, indeed, on the cell types, the environment in which the cells reside (*e.g.* the environment *in vivo* or ordinary *in vitro* culture conditions) as well as on the means, extent and duration of the inhibition [of] *Hh/Smo* signaling."

Clearly then, the induction of differentiation and/or apoptosis in tumor cells that use *Hh/Smo* signaling by contacting the tumor cells with "a sufficient quantity of cyclopamine" to induce cellular differentiation and/or apoptosis of said tumor cells, particularly in humans, is extremely unpredictable. It is clear from the prior art that simply inhibiting *Hh/Smo* signaling with cyclopamine is not sufficient to induce differentiation and/or apoptosis of cells. Further, amounts of cyclopamine that are "sufficient" to inhibit *Hh/Smo* signaling and cell proliferation of a certain cell type are not, *a priori*, sufficient to induce differentiation and/or apoptosis of the same cells.

2. The breadth of the claims

The claims vary in breadth; some (such as claim 1) vary broadly, reciting the induction of cellular differentiation and/or apoptosis of "tumor cells". Others, such as claim 4, are narrower, reciting "basal cell carcinoma".

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for determining the particular administration regimes (dosages, timing, administration routes, etc.) necessary to induce differentiation and/or apoptosis in all tumors that use *Hh/Smo* signaling for inhibition of differentiation and/or for inhibition of apoptosis, particularly in humans. The working examples are limited to inducing differentiation and/or apoptosis of basal cell carcinoma (BCC) through topical administration of cyclopamine. Thus, the applicant at best has provided specific direction or guidance only for the treatment of BCC through topical application. No reasonably specific guidance is provided concerning useful therapeutic protocols for any other tumors, administration routes, doses or derivatives of cyclopamine. It is noted that applicants only discuss specific doses for topical administration but not for the other routes of administration instantly claimed. Claim 1 recites "a sufficient quantity" of cyclopamine "to induce cellular differentiation and/or apoptosis of said tumor cells". While the phrase "sufficient quantity" meets the requirements of 35 U.S.C. 112, 2nd; without further elaboration and support in the specification, "sufficient quantity" does not provide adequate enablement for the claimed methods. This is especially true given the unpredictable nature of the art as discussed *supra*.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims (*i.e.* demonstration of efficacy in a representative sample of different tumor cells), the skilled artisan would not accept the assertion that the instantly claimed methods could be predictably used to induce differentiation and/or apoptosis of any tumor cells that use *Hh/Smo* signaling for inhibition of differentiation and/or for inhibition of apoptosis, particularly in humans, as inferred in the claims and contemplated by the specification.

As discussed *supra*, and disclosed in applicant's replies to previous Office Actions, the response of cells to cyclopamine depend on numerous factors (*e.g.* cell type, cellular environment, and the means, extent and duration of *Hh/Smo* inhibition). Applicant's disclosure does not provide adequate enablement with respect to the means, extent, duration and dose required to induce differentiation and/or apoptosis of any and all tumor cells that use *Hh/Smo* signaling for inhibition of differentiation and/or for inhibition of apoptosis as instantly claimed.

Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 1-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims, *via* claim 1, lines 4-5, include derivatives of cyclopamine. Such derivatives are defined on page 10, lines 8-26, to include optional molecular groups, but only those found via testing. Testing to find derivatives is insufficient to provide written description basis for contemplation of chemical formulas for such derivatives.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of the complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present is that the derivative binds specifically to the same biological target as cyclopamine. There is no description of structural characteristics that are required to retain biological activity. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 111, clearly states, “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed *supra*, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of derivatives of cyclopamine, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or synthesizing it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only cyclopamine, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes it clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see *Vas-Cath* at page 1115). See also *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement).

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant case, claim 2 recites the comparative limitation "smaller proportion" in lines 2-3. This limitation renders the claim indefinite because it is not clear what the proportion is smaller compared to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 8-12 are again rejected under 35 U.S.C. § 103(a) as being unpatentable over Dudek *et al.* (prior art of record).

Dudek *et al.* disclose a method for "inhibiting aberrant growth states resulting from *hedgehog* gain-of-function, ptc loss of function or smoothened gain-of-function" comprising contacting a cell with a compound in an amount sufficient to control the aberrant growth state, e.g., to agonize a normal ptc pathway or antagonize smoothened or *hedgehog* activity (Abstract). Cyclopamine is disclosed in Figure 1 and is shown to reduce medulloblastoma tumor volume *in vivo* (Figure 3). The invention disclosed is also drawn to "treating or preventing basal cell carcinoma" (col. 13, line 31). The invention of Dudek *et al.* also contemplates regulation of the *hedgehog* pathway, e.g., proliferation or other biological consequences of misexpression of, for example, ptc, *hedgehog* or smoothened (col. 15, lines 60-64). An "effective amount" is defined the amount of an antagonist which brings about "a change in the rate of cell proliferation and/or the state of differentiation of a cell and/or rate of survival of a cell" (col. 17, lines 26-33). Dudek *et al.* specifically contemplate a method of "modulating a differentiated state, survival, and/or proliferation of a cell having ptc loss-of-function, *hedgehog* gain-of-function, or smoothened gain-of-function" by contacting cells with a compound such as cyclopamine (col. 38, lines 15-21). The subject method can also be used to induce differentiation and/or inhibit proliferation of epithelially derived tissue such as various skin cancers, including basal cell carcinoma (col. 50, lines 47-65). Treatment of basal cell carcinoma is further exemplified in column 52, lines 6-45.

Dudek *et al.* also disclose the administration methods recited in instant claims 5-6 and 8-12. For example, the reference discloses formulations for administration of the disclosed compounds with a biologically acceptable medium such as water, buffered saline, polyol, and mixtures thereof (col. 53, lines 16-22). Further, routes of administration include oral, parenteral (including injection), topical and rectal (col. 53, lines 54-55). Controlled release patches, ointments, tablets and capsules are disclosed (col. 53, lines 55-61).

Applicant's arguments have been duly considered but they are not deemed to be persuasive. Applicants argue, *inter alia*, that the skilled artisan can practice the methods of Dudek *et al.* without obtaining the results specified in instant claim 1. Claim 1 is drawn to the administration of cyclopamine in an amount effective to "induce cellular differentiation and/or apoptosis" of tumor cells. As cited above, Dudek *et al.* disclose the same method steps, i.e. administration of cyclopamine in an effective amount defined as the amount of an antagonist which brings about "a change in the rate of cell proliferation and/or the state of differentiation of a cell and/or rate of survival of a cell". A change in the state of differentiation would include inducing differentiation. Further, a change in the rate of survival of a cell includes inducing apoptosis. It is respectively submitted that applicants are inappropriately attempting to limit the methods of Dudek *et al.* to inhibition of cell proliferation when Dudek clearly discloses methods which change the state of differentiation (*i.e.* inducing) and rate of cell survival (*i.e.* apoptosis).

Concerning the method claims, from the standpoint of patentability, methods steps must distinguish over the prior art in terms of method steps, i.e. the acts or series of acts involved in the method. Please see *Ex parte Forsyth et al.*, 151 USPQ 55 (BPAI 1966). The examiner respectfully submits that applicants have not clearly distinguished the claimed method steps from the method steps disclosed in Dudek *et al.* Claim 1 of the instant application recites a method for inducing cellular differentiation and/or apoptosis in tumor cells that use Hedgehog/smoothened signaling, wherein the act or series of acts comprise contacting tumor cells with a sufficient quantity of cyclopamine or a derivative thereof. Dudek *et al.* disclose the identical act or series of acts required by the claims. For example, Dudek *et al.*, disclose a method of treating tumors or basal cell carcinoma (as recited in claim 4 of the instant application) by administering to a patient in need thereof (i.e. *in vivo*) an effective amount of cyclopamine. More specifically, Dudek *et al.* disclose treating mice suffering from medullblastoma by administering to the mice an effective amount of cyclopamine, wherein the cyclopamine inhibited the tumor growth (Figure 3).

Finally, absent evidence to the contrary, it is reasonable to conclude that the same patient is being administered the same composition, i.e. cyclopamine, by the same mode of administration in the same effective amount in both the instant claims and the Dudek *et al.* reference. The fact that applicant may have discovered yet another beneficial effect from the method, i.e. induction of cellular differentiation and/or apoptosis, set forth in the prior art does not mean that they are entitled to received a patent on the method.

> "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruft* 16 USPQZd 1934, 1936 (Fed. Cir. 1990).

Also, it does not appear that the instant claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Please see *Bristol-Meyers Squibb Co. v. Ben Venue Laboratories*, 58 USPQZd 1508 (CAFC 2001).

Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Dudek *et al.* as applied to claims 1-6 and 8-12 above, and further in view of Keller *et al.* (U.S. Patent No. 5,891,465; Issued April 6, 1999).

Dudek *et al.* disclose as above.

Keller *et al.* disclose the administration of pharmacologically active agents in liposomal formulations (col. 1, lines 7-16). Liposomal formulations of active agents are beneficial in that they are non-invasive, provide enhanced absorption properties of the agent and provide from about 20 to 100% increase in the bioavailability of the active agent (col. 8, lines 1-12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer cyclopamine in a liposomal carrier in view of the Dudek and Keller disclosures. The motivation to do so is found in Keller *et al.* wherein it is disclosed that a 20 to 100% increase in bioavailability can be obtained when pharmacologically active agents are encapsulated in liposomes. Thus, the skilled artisan would be imbued with at least a reasonable expectation that the bioavailability and absorption properties of cyclopamine would be enhanced if it were administered in the liposome carriers of the Keller *et al.* reference.

Pertinent Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent Nos. 6,432,970, 6,686,388 and 6,867,216 disclose methods similar to the Dudek *et al.* reference. More specifically, the '970, '388 and '216 patents all disclose methods wherein cyclopamine is administered in the treatment of basal cell carcinoma.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

August 16, 2006

Ardin H. Marschel 9/3/06
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SUPERVISORY PATENT EXAMINER